STATE OF MISSOURI MISSOURI BOARD OF PHARMACY

IN RE:)	
)	
ST. CLAIR COUNTY HOSPTIAL)	
DISTRICT #1 d/b/a)	
SAC-OSAGE HOSPTIAL)	Complaint No. 2011-000189
Permit #004315	í	•

SETTLEMENT AGREEMENT BETWEEN STATE BOARD OF PHARMACY AND ST. CLAIR COUNTY HOSPITAL DISTRICT #1 d/b/a SAC-OSAGE HOSPITAL

Come now St. Clair County Hospital District #1 d/b/a Sac-Osage Hospital, ("Respondent" or "Licensee") and the Missouri Board of Pharmacy ("Board" or "Petitioner") and enter into this Settlement Agreement for the purpose of resolving the question of whether Respondent's permit to operate a pharmacy will be subject to discipline.

Pursuant to the terms of Section 536.060, RSMo, the parties hereto waive the right to a hearing by the Administrative Hearing Commission of the State of Missouri and, additionally, the right to a disciplinary hearing before the Board under Section 621.110, RSMo, and stipulate and agree that a final disposition of this matter may be effectuated as described below.

Respondent acknowledges that it understands the various rights and privileges afforded it by law, including the right to a hearing of the charges against it; the right to appear and be represented by counsel; the right to have all charges against it proved upon the record by competent and substantial evidence; the right to cross-examine any witnesses appearing at the hearing against it; the right to a decision upon the record by a fair and impartial administrative hearing commissioner concerning the charges pending against it and, subsequently, the right to a disciplinary hearing before the Board at which time it may present evidence in mitigation of discipline; and the right to recover attorney's fees incurred in defending this action against its

permit. Being aware of these rights provided it by operation of law, Respondent knowingly and voluntarily waives each and every one of these rights and freely enters into this Settlement Agreement and agrees to abide by the terms of this document as they pertain to it.

Respondent acknowledges that it has received a copy of the draft complaint to be filed with the Administrative Hearing Commission, the investigative report, and other documents relied upon by the Board in determining there was cause for discipline against Respondent's permit.

For the purpose of settling this dispute, Respondent stipulates that the factual allegations contained in this Settlement Agreement are true and stipulates with the Board that Respondent's permit to operate a pharmacy, numbered 004315, is subject to disciplinary action by the Board in accordance with the provisions of Chapter 621 and Chapter 338, RSMo.

JOINT STIPULATION OF FACTS

- 1. The Missouri Board of Pharmacy is an agency of the State of Missouri created and established pursuant to Section 338.110, RSMo¹, for the purpose of executing and enforcing the provisions of Chapter 338, RSMo.
- 2. St. Clair County Hospital District #1 d/b/a Sac-Osage Hospital ("Respondent" or the "Pharmacy"), Junction Highway 13 & Old Hwy 82, Osceola, Missouri, was permitted as a Class B Hospital Pharmacy, License Number 004315. Respondent's permit was at all times relevant herein, current and active.
- 3. S.W. was employed by the Pharmacy as a pharmacy technician at all times relevant herein. S.W. was at no time and is not currently a licensed pharmacist in the state of Missouri.

¹ All statutory references are to the 2000 Revised Statutes of Missouri, as amended, unless otherwise stated.

- 4. On January 24, 2011, the Board's Compliance Officer, Jason Menken, received an e-mail correspondence from Respondent's pharmacist in charge D.H. explaining two situations, the first occurred when a technician dispensed prescriptions to a hospital board member who presented a valid prescription for his wife when no pharmacist was on duty, and the second occurred when the same technician dispensed several pills to a hospital employee to get her through the weekend when a pharmacist would be back on duty.
- 5. On February 23, 2011, Inspector Frank Van Fleet visited the Pharmacy and discussed the incidents with D.H.
- 6. D.H. informed Inspector Van Fleet that the first incident in which technician S.W. dispensed without a pharmacist on duty was on September 21, 2009. At that time, a hospital board member requested that S.W. fill a valid prescription written for his wife despite the fact that a pharmacist was not on duty.
- 7. D.H. did not report the incident at the time because he felt that the board member had pressured S.W. into filling the prescription. Instead, he discussed the incident with S.W., the hospital Chief Executive Officer, and the Director of Nursing informing them that technicians should not be pressured into dispensing prescriptions without a pharmacist on duty.
- 8. Additionally, D.H. had S.W. document the incident in an undated writing in which S.W. admitted that she dispensed one Levaquin 500mg and 5 Albuterol when a pharmacist was not present in the pharmacy.
- 9. D.H. told Inspector Van Fleet that he decided to report the September 21, 2009 incident after the second incident involving S.W. occurred at the pharmacy.
- 10. On May 20, 2010, a hospital employee came to the Pharmacy to pick up a prescription at around 3:30 p.m. after D.H. had left the Pharmacy. S.W. gave the employee three

capsules of Gabapentin, pursuant to prescription number 1000008546, dated May 20, 2010 for 30 Neurontin 300mg, to get her through the weekend until a pharmacist would be on duty to fill the full prescription.

- 11. D.H. only discovered the three unauthorized capsules of Gabapentin when the employee came to the Pharmacy on May 24, 2010, to fill prescription 1000008546, and asked D.H. to leave three capsules out of the prescription because S.W. had already given them to her.
- 12. Even though S.W. dispensed three capsules on May 20, 2010, the Pharmacy computer system shows that prescription number 1000008546, dated May 20, 2010 for 30 Neurontin 300mg was filled, dispensed and billed on May 24, 2010.
- 13. Inspector Van Fleet interviewed S.W. and she admitted to dispensing legend drugs to the hospital board member without a pharmacist on duty. S.W. claimed to not remember the second incident.
- 14. Missouri law prohibits a pharmacy technician from dispensing prescription drugs without a pharmacist on duty, to wit:
 - pharmacy" 1. "practice of means the interpretation, implementation, and evaluation of medical prescription orders, including any legend drugs under 21 U.S.C. Section 353; receipt, transmission, or handling of such orders or facilitating the dispensing of such orders; the designing, initiating, implementing, and monitoring of a medication therapeutic plan as defined by the prescription order so long as the prescription order is specific to each patient for care by a pharmacist; the compounding, dispensing, labeling, and administration of drugs and devices pursuant to medical prescription orders and administration of viral influenza, pneumonia, shingles and meningitis vaccines by written protocol authorized by a physician for persons twelve years of age or older as authorized by rule or the administration of pneumonia, shingles, and meningitis vaccines by written protocol authorized by a physician for a specific patient as authorized by rule; the participation in drug selection according to state law and participation in drug utilization reviews; the proper and safe storage of drugs and devices and the maintenance of proper records

thereof; consultation with patients and other health care practitioners, and veterinarians and their clients about legend drugs, about the safe and effective use of drugs and devices; and the offering or performing of those acts, service, operations, or transactions necessary in the conduct, operation, management and control of a pharmacy. No person shall engage in the practice of pharmacy unless he is licensed under the provisions of this chapter. ... §338.010.1, RSMo.

- 15. Missouri law provides further guidance, to wit:
 - (B) Whenever, in a pharmacy or other establishment holding a Missouri pharmacy permit, a person other than a licensed pharmacist does compound, dispense or in any way provide any drug, medicine or poison pursuant to a lawful prescription, a licensed pharmacist must be physically present within the confines of the dispensing area, able to render immediate assistance and able to determine and correct any errors in the compounding, preparation or labeling of that drug, medicine or poison before the drug, medicine or poison is dispensed or sold. . . . 21 CSR 2220-2.010(1)(B).
- 16. Pharmacy technician dispensed legend drugs in the Pharmacy on at least two occasions without a pharmacist on duty or present in the Pharmacy in violation of §338.010.1, RSMo and 21 CSR 2220-2.010(1)(B).

Cause to Discipline

- 17. Cause exists to discipline Respondent's permit to operate a pharmacy under §338.210.5, RSMo, which provides:
 - 5. If a violation of this chapter or other relevant law occurs in connection with or adjunct to the preparation or dispensing of a prescription or drug order, any permit holder or pharmacist-incharge at any facility participating in the preparation, dispensing, or distribution of a prescription or drug order may be deemed liable for such violation. §338.210.5, RSMo.
- 18. Cause exists to discipline Respondent's permit to operate a pharmacy under 20 CSR 2220-2.010(1)(O):

- (O) When a pharmacy permit holder knows or should have known, within the usual and customary standards of conduct governing the operation of a pharmacy as defined in Chapter 338, RSMo, that an employee, licensed or unlicensed, has violated the pharmacy laws or rules, the permit holder shall be subject to discipline under Chapter 338, RSMo.
- 19. Respondent's conduct is also cause for disciplinary action against its pharmacy permit under §338.055 RSMo, which provides:
 - 2. The board may cause a complaint to be filed with the administrative hearing commission as provided by chapter 621, RSMo, against any holder of any certificate of registration or authority, permit or license required by this chapter or any person who has failed to renew or has surrendered his or her certificate of registration or authority, permit or license for any one or any combination of the following causes:
 - (5) Incompetence, misconduct, gross negligence, fraud, misrepresentation or dishonesty in the performance of the functions or duties of any profession licensed or regulated by this chapter;
 - (6) Violation of, or assisting or enabling any person to violate, any provision of this chapter, or of any lawful rule or regulation adopted pursuant to this chapter;
 - (13) Violation of any professional trust or confidence;
 - (15) Violation of the drug laws or rules and regulations of this state, any other state or the federal government; §338.055.2(5), (6), (13), and (15), RSMo.

JOINT AGREED DISCIPLINARY ORDER

Based upon the foregoing, the parties mutually agree and stipulate that the following shall constitute the disciplinary order entered by the Board in this matter under the authority of Section 621.045.3, RSMo:

- A. Respondent's pharmacy permit numbered 004315, is hereby PUBLICLY CENSURED.
- B. The terms of this Settlement Agreement are contractual, legally enforceable, binding, and not merely recitals. Except as otherwise contained herein, neither this Settlement Agreement nor any of its provisions may be changed, waived, discharged, or terminated, except by an instrument in writing signed by the party against whom the enforcement of the change, waiver, discharge, or termination is sought.
- C. Respondent, together with its heirs and assigns, and its attorneys, does hereby waive and release the Board, its members and any of its employees, agents, or attorneys, including any former board members, employees, agents, and attorneys, of, or from, any liability, claim, actions, causes of action, fees, costs and expenses, and compensation, including, but not limited to any claims for attorney's fees and expenses, including any claims pursuant to Section 536.087, RSMo, or any claim arising under 42 U.S.C. Section 1983, which may be based upon, arise out of, or relate to any of the matters raised in this litigation, or from the negotiation or execution of this Settlement Agreement. The parties acknowledge that this paragraph is severable from the remaining portions of this Settlement Agreement in that it survives in perpetuity even in the event that any court of law deems this Settlement Agreement or any portion thereof void or unenforceable.

RESPONDENT, AS EVIDENCED BY THE INITIALS ON THE APPROPRIATE LINE,

REQUESTS

DOES NOT REQUEST

THE ADMINISTRATIVE HEARING COMMISSION TO DETERMINE IF THE FACTS SET FORTH HEREIN ARE GROUNDS FOR DISCIPLINING RESPONDENT'S PERMIT TO OPERATE A PHARMACY.

If Respondent has requested review, Respondent and Board jointly request that the Administrative Hearing Commission determine whether the facts set forth herein are grounds for disciplining Respondent's permit and issue findings of fact and conclusions of law stating that the facts agreed to by the parties are grounds for disciplining Respondent's permit. Effective fifteen (15) days from the date the Administrative Hearing Commission determines that the Settlement Agreement sets forth cause for disciplining Respondent's permit, the agreed upon discipline set forth herein shall go into effect.

If Respondent has not requested review by the Administrative Hearing Commission, the Settlement Agreement goes into effect fifteen (15) days after the document is signed by the Board's Executive Director.

RESPONDENT

ST. CLAIR COUNTY HOSPTIAL DISTRICT #1 d/b/a SAC-OSAGE HOSPTIAL

By:

as Authorized Representative for: ST. CLAIR COUNTY HOSPTIAL DISTRICT #1 d/b/a SAC-OSAGE HOSPTIAL

Date: 04-18-2012

PETITIONER

MISSOURI BOARD OF

PHARMACY

Kimberly Grinston Executive Director

Date: 5-7-12

NEWMAN, COMLEY & RUTH P.C.

By:

Joshua L. Hill

#62951

P.O. Box 537

Jefferson City, Missouri 65102-0537 Telephone: (573) 634-2266

Fax: (573) 636-3306 hilli@ncrpc.com

Attorneys for Missouri Board of Pharmacy